

Claims

We Claim:

1. A method of treating an animal with cancer who has received an allogeneic hematopoietic cell transplant, comprising administering to said animal an amount of an oral topically active corticosteroid effective to prevent or reduce symptoms of GVHD while maintaining a GVL reaction effective to eliminate or reduce the number of cancer cells in the blood of said animal.
2. The method of claim 1, wherein said animal is a human.
3. The method of claim 1, wherein said topically active corticosteroid is administered in at least two different dosage forms.
4. The method of claim 1 wherein the topically active corticosteroid is administered orally at a dosage of between about 0.1 mg per day to about 8 mg per day.
5. The method of claim 1 wherein the topically active corticosteroid is administered orally at a dosage of between about 2 mg per day to about 4 mg per day.
6. The method of claim 1 wherein the topically active corticosteroid is administered orally from day 1 to about day 80 following hematopoietic cell transplantation.
7. The method of claim 1 wherein the topically active corticosteroid is administered in combination with prednisone or prednisolone at a concentration of at least 1 mg/kg body weight/day.
8. The method of claim 1 wherein the topically active corticosteroid is formulated for oral administration in the form of a pill, tablet, capsule or microsphere.

Docket 266/067

9. The method of claim 8 wherein the topically active corticosteroid is formulated such that the pill, microsphere, or capsule dissolves in the stomach, small intestine or colon.
10. The method of claim 1 wherein the topically active corticosteroid is formulated for oral administration in the form of an emulsion.
11. The method of claim 1 wherein said topically active corticosteroid is administered following infusion of the hematopoietic cells.
12. The method of claim 1 wherein administration of the topically active corticosteroid ceases after 80 days following infusion of the hematopoietic cells.
13. The method of claim 1 wherein the patient has received an allogeneic bone marrow transplant.
14. The method of claim 1 wherein the patient has received an allogeneic blood transplant.
15. The method of claim 1 wherein the topically active corticosteroid is administered in combination with at least one of cyclosporine, methotrexate, tacrolimus, anti-lymphocyte globulin, anti-T-cell monoclonal antibodies and anti-T-cell immunotoxins.
16. The method of claim 1 wherein the topically active corticosteroid is beclomethasone 17,21-dipropionate.
17. The method of claim 1 wherein the topically active corticosteroid is alclometasone dipropionate, busedonide, 22S busedonide, 22R busedonide, beclomethasone-17-monopropionate, clobetasol propionate, diflorasone diacetate,

TOP SECRET - 06382660

flunisolide, flurandrenolide, fluticasone propionate, halobetasol propionate, halcinocide, mometasone furoate, or triamcinolone acetonide.

18. A method of treating an animal who has received an organ allograft transplant, comprising administering to said animal an amount of an oral topically active corticosteroid effective to prevent or reduce symptoms of HVGD.

TOP SECRET - 069382660